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EXAMINER	
REIDEL, JESSICA L	
ART UNIT	PAPER NUMBER
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,950	XUE ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement of Applicant's Amendment, received by the Office on October 10, 2006 is made. Claims 2 and 20 were previously cancelled. Claims 1 and 3-19 are pending.

Drawings

2. In view of the response filed on October 10, 2006, the objections to the drawings made in the Office Action of July 5, 2006 have been withdrawn.

Specification

3. In view of the response filed on October 10, 2006, the objections to the specification made in the Office Action of July 5, 2006 have been withdrawn.

Claim Objections

4. In view of the response filed on October 10, 2006, the objections to the claims made in the Office Action of July 5, 2006 have been withdrawn.

5. Claim 3 is objected to because of the following informalities: there appears to be a typographical error in the second line of the claim. The Examiner suggest changing "QRS-T angle" to read, "3-D QRS-T angle" instead in order to provide consistency in the claim language and to avoid and antecedent basis problem. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. In view of the response filed on October 10, 2006, the 35 U.S.C. 112 rejections made in the Office Action of July 5, 2006 have been withdrawn.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1 and 3-19 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. After reconsideration of the claimed subject matter, the Examiner deems that all of Applicants' claims are directed to a judicial exception of 35 U.S.C. 101. The method claims of the present application relate to an abstract idea, rather than a practical application of that idea. Specifically, the claims do not require any physical transformation and the invention as claimed does not produce a useful, concrete, and tangible result. See MPEP § 706.03(a). To overcome this rejection, the Examiner recommends adding a tangible, useful and concrete method step wherein the method "employs" the "calculating"/"analyzing" by "performing an action" or "completing a method step". To explain further and/or clarify, the Examiner notes that a physician/clinician has the ability to "calculate a variation between the first value and the second value" using his mind. The Examiner suggests changing the last line of Claim 1 to read something similar to, "calculating a variation between the first value and the second value and outputting said calculated variation to an output device". This produces a physical transformation and provides a useful, concrete and tangible result (i.e. the output). The language

of Claim 18 should be modified similarly to add a physical transformation and/or produce a useful, concrete and tangible result.

Response to Arguments

9. Applicant's arguments, see pages 8-9, filed October 10, 2006, with respect to the rejection(s) of claim(s) s 1 and 3 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kardys et al. *Spatial QRS-T angle predicts cardiac death in a general population* European Heart Journal (2003) 24, 1357-1364 (herein Kardys).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 3 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (U.S. 4,136,690) (herein Anderson) in view of Kardys. As to Claims 1 and 3, Anderson discloses a method using an electrocardiogram (ECG) signal comprising measuring a 2-D QRS-T angle, read as defining a relationship, between the QRS peak vector, read as depolarization, and the T-wave peak vector, read as repolarization. Anderson discloses that the 2-D QRS-T angle is "successively stored" and the Examiner interprets this to mean that the 2-D QRS-T angle is determined for a first beat of the ECG, a second beat of the ECG and successive beats of the ECG (see Anderson column 2, lines 19-50 and column 3, lines 8-64). Anderson further discloses that each stored 2-D QRS-T angle is tallied into one of a number of angular ranges for analysis and comparison between ranges, read as calculating a variation between the successfully stored values (see Anderson column 3, lines 57-67, column 7, lines 43-47 and column 8, lines 59-66). It is inherent or at least obvious to one having ordinary skill in the art at the time the invention was made that, although not expressly disclosed by Anderson, the accumulated data stored, displayed or printed and used for analysis in the method of Anderson assesses a patient's cardiac vulnerability to sudden cardiac death because any arrhythmias present in the vectorcardiograph can be detected and classified and arrhythmias are a well known precursor to sudden cardiac death. The Examiner takes the position that a method, which classifies arrhythmias present in a patient's ECG signal, inherently assesses "vulnerability" to "sudden cardiac death" since an arrhythmia present in a patient's ECG indicates that a patient is more "vulnerable" to experiencing "sudden cardiac death". Anderson discloses the claimed

invention as discussed above except that it is not specified that the method calculate a 3-D QRS-T angle from a set of orthoganalized X, Y and Z leads of the ECG and then use the 3-D QRS-T angle to asses a patient's cardiac vulnerability to sudden cardiac death by calculating a variation between successively calculated 3-D QRS-T angles.

Kardys, however, teaches that the spatial QRS-T angle, read as the 3-D QRS-T angle since it is disclosed to be calculated from a set of orthoganalized X, Y and Z leads of the ECG, is a strong and independent predictor of cardiac mortality that is less susceptible to noise. Kardys also discloses that calculation of the 3-D QRS-T angle can be easily implemented on modern electrocardiographs, which are nowadays equipped with sufficient computing power. Kardys teaches that the abnormal 3-D QRS-T angles are associated with worse cardiac outcomes such as fatal cardiac events (see Kardys pages 1357-1364). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys to utilize a 3-D QRS-T angle calculated from a set of orthoganalized X, Y and Z leads of the ECG since such a modification would allow for assessment a patient's worsening condition and since such a modification may be easily implemented and is less susceptible to noise.

13. As to Claims 6 and 7, the previously modified Anderson reference discloses the claimed invention except the method does not specify selecting the first beat and the second beat from median beats or mean beats. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson in view of Kardys to include selecting the first beat and the second beat from median or mean beats since it was

known in the art that such a statistical selection method is used to provide means for lessening the affect that spurious signals have on the diagnosis results.

14. Claims 4-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of Burnes (U.S. 2004/0220635). As to Claims 4 and 5, the previously modified Anderson reference discloses the claimed invention as discussed above except that it is not specified that the method include defining the relationship between depolarization and repolarization to include a QRS duration and a T/QT duration.

Burnes, however, discloses a method using an ECG comprising determining an activation recovery interval (ARI), read as a relationship, as the difference between activation time, read as depolarization, and recovery time, read as repolarization (see Burnes page 8, Claim 6). Burnes also discloses that if a subsequent comparison of a prior dispersion of ARI reveals an increased dispersion of ARI, a worsening heart failure condition is declared (see Burnes page 5, paragraphs 48-51). It is inherent that the subsequent ARI is determined for a first beat and the prior dispersion of ARI determined for a second beat. It is inherent or at least obvious to one having ordinary skill in the art at the time the invention was made that, although not expressly disclosed by Burnes, the detection of increased dispersion disclosed is capable of assessing a patient's cardiac vulnerability to sudden cardiac death because the method indicates a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death. In addition the detection of increased dispersion disclosed by Burnes is inherently indicative of an increased "vulnerability" to "sudden cardiac death". Burnes further discloses that determination of the dispersion of the ARI includes QRS duration and QT duration and QRS

duration and T duration (see Burnes page 1, paragraphs 3-5 and page 6, paragraphs 53-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys and Burnes to include defining the relationship between depolarization and repolarization to further include QRS duration and T/QT duration in order to provide indication of a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death.

15. As to Claim 8, the previously modified Anderson reference discloses the claimed invention as discussed above except that it is not specified that the first beat be within a first range of heart rate and the second beat be within a second range of heart rate that is different from the first.

Burnes, however, discloses a method using an ECG comprising determining an activation recovery interval (ARI), read as a relationship, as the difference between activation time, read as depolarization, and recovery time, read as repolarization (see Burnes page 8, Claim 6). Burnes also discloses that if a subsequent comparison of a prior dispersion of ARI reveals an increased dispersion of ARI, a worsening heart failure condition is declared (see Burnes page 5, paragraphs 48-51). It is inherent that the subsequent ARI is determined for a first beat and the prior dispersion of ARI determined for a second beat. It is inherent or at least obvious to one having ordinary skill in the art at the time the invention was made that, although not expressly disclosed by Burnes, the detection of increased dispersion disclosed is capable of assessing a patient's cardiac vulnerability to sudden cardiac death because the method indicates a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death. In addition the detection of increased dispersion disclosed by Burnes is inherently

indicative of an increased "vulnerability" to "sudden cardiac death". Burnes further discloses that dispersion measurements may be performed on a periodic basis for monitoring heart failure status, monitoring arrhythmia risk, or optimizing a therapy in order to reduce dispersion, for example by adjusting cardiac pacing parameters during CRT or adjusting the dosage of a drug therapy (see Burnes page 5, paragraph 47). It is inherent the such an optimization would include selecting a first beat from an ECG signal obtained from the patient prior to the event and selecting the second beat from an ECG signal obtained from the patient after the event. It is also inherent that a first beat selected in this manner would be from an ECG having a heart rate within a first range and a second beat selected in this manner would be from an ECG having a heart rate within a second range that is different from the first due to the administered therapy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson in view of Kardys and Burnes to include a step of selecting the first beat from an ECG obtained from the patient prior to an event and selecting the second beat from an ECG obtained from the patient after the event where the event includes administering a pharmaceutical drug to a patient in order optimize the invention.

16. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of Kaplan et al. (U.S. 4,732,157) (herein Kaplan). The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not further comprise conduction a time series analysis of the first and second values.

Kaplan, however, teaches that is known to use a time series to quantify beat-to-beat variability in an ECG waveform in order to determine susceptibility to ventricular fibrillation

(see Kaplan column 5, lines 12-23 and column 6, lines 1-22). Kaplan also discloses that an objective of the time series analysis on a plurality of beats is to derive a numerical parameter from the ECG, which is associated with susceptibility to ventricular fibrillation (see Kaplan Abstract and column 2, lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys and Kaplan to include a time series analysis in order to derive a numerical parameter associated with susceptibility to ventricular fibrillation.

17. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of Verrier et al. (U.S. 5,265,617) (herein Verrier '617). The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not further comprise using a cardiac parameter or heart rate variability in addition to the ECG signal to asses the patient's cardiac vulnerability to sudden cardiac death.

Verrier '617, however, discloses a method and apparatus for the non-invasive diagnosing of cardiac vulnerability to ventricular fibrillation that comprises evaluating heart rate variability in addition to T-wave alternans of the ECG signal (see Verrier '617 Title and Abstract). Verrier '617 discloses that heart rate variability is a measure of autonomic influence, which is a major factor in triggering cardiac arrythmias and that by simultaneous analysis of the ECG signal and heart rate variability allows for the extent and cause of cardiac vulnerability to be assessed so that drug therapy may be tailored per patient (see Verrier '617 column 4, lines 54-67 and column 5, lines 1-5). The Examiner takes the position that heart rate variability is synonymous with a cardiac parameter. Therefore, it would have been obvious to one having ordinary skill in the art

at the time the invention was made to modify the method of Anderson in view of Kardys and Verrier '617 to include simultaneous evaluation of heart rate variability in addition to the ECG signal to better asses the patient's vulnerability to sudden cardiac death and to tailor a drug therapy as best to treat the patient.

18. Claims 12 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of Ralph et al "Blunted arterial baroreflec causes 'pathological' heart rate turbulence", cited by Applicant (herein Ralph). The previously modified Anderson discloses the claimed invention as discussed above except that the method does not further comprise using heart rate turbulence in addition to the ECG signal.

Ralph, however, teaches that it is known to utilize a characteristic of baroreflex function such as heart rate turbulence (either onset or slope) as set forth in the Abstract and the third paragraph on page 2, as a superior predictor of sudden cardiac death. In particular, Ralph discloses that turbulence onset is defined prior to a premature ventricular contraction and after the premature ventricular contraction and turbulence slope is defined within the first 20 sinus-rhythm intervals after the premature contraction. The Examiner takes the position that PVCs naturally have varying cycle lengths and varying morphologies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson in view of Kardys, to include heart rate turbulence in addition to analysis of the ECG signal as taught by Ralph, since such a modification would provide a substantial improvement in the ability to predict sudden cardiac death.

19. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys and Ralph as applied to claims 1 and 12 above, and further in view of Verrier et al. (U.S. 5,560,370) (herein Verrier '370). The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not comprise using data corresponding to blood pressure change in addition to heart rate turbulence to asses the patient's cardiac vulnerability to sudden cardiac death.

Verrier '370, however, discloses a method for prediction of cardiac electrical instability that uses baroreflex sensitivity as an additional indicator of cardiac electrical instability and that this sensitivity may be non-invasively characterized as blood pressure (see Verrier '370 column 20, lines 34-45). It would have been obvious to one having ordinary skill in the art to modify the method of Anderson in view of Kardys, Ralph and Verrier to include using data corresponding to blood pressure in addition to heart rate turbulence to non-invasively asses the patient's cardiac vulnerability to sudden cardiac death.

20. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys and Ralph as applied to claims 1 and 12 above, and further in view of Burnes. The previously modified Anderson reference discloses the claimed invention except that selecting the first beat from an electrocardiogram signal obtained from the patient is not disclosed to occur prior to an event and selecting the second beat from an electrocardiogram signal obtained from the patient is not disclosed to occur at least one of during and after the event where the event includes at least one of administering a pharmaceutical drug to a patient, pacing the patient using exercise, and pacing the patient using an implanted pacemaker.

Burnes, however, discloses a method using an ECG comprising determining an activation recovery interval (ARI), read as a relationship, as the difference between activation time, read as depolarization, and recovery time, read as repolarization (see Burnes page 8, Claim 6). Burnes also discloses that if a subsequent comparison of a prior dispersion of ARI reveals an increased dispersion of ARI, a worsening heart failure condition is declared (see Burnes page 5, paragraphs 48-51). It is inherent that the subsequent ARI is determined for a first beat and the prior dispersion of ARI determined for a second beat. In addition the detection of increased dispersion disclosed by Burnes is capable of assessing a patient's cardiac vulnerability to sudden cardiac death because the method indicates a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death. Bunres also discloses that dispersion measurements may be performed on a periodic basis for monitoring heart failure status, monitoring arrhythmia risk, or optimizing a therapy in order to reduce dispersion, for example by adjusting cardiac pacing parameters during CRT or adjusting the dosage of a drug therapy (see Burnes page 5, paragraph 47). It is inherent the such an optimization would include selecting a first beat from an ECG signal obtained from the patient prior to the event and selecting the second beat from an ECG signal obtained from the patient after the event. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson in view of Kardys, Ralph and Burnes to include a step of selecting the first beat from an ECG obtained from the patient prior to an event and selecting the second beat from an ECG obtained from the patient after the event where the event includes administering a pharmaceutical drug to a patient in order optimize the invention.

21. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys and Kaplan. Anderson discloses a method using an electrocardiogram (ECG) signal comprising measuring a 2-D QRS-T angle, read as defining a relationship, between the QRS peak vector, read as depolarization, and the T-wave peak vector, read as repolarization. Anderson discloses that the 2-D QRS-T angle is "successively stored" and the Examiner interprets this to mean that the 2-D QRS-T angle is determined for a first beat of the ECG, a second beat of the ECG and successive beats of the ECG (see Anderson column 2, lines 19-50 and column 3, lines 8-64). Anderson further discloses that each stored 2-D QRS-T angle is tallied into one of a number of angular ranges for analysis and comparison between ranges, read as calculating a variation between the successfully stored values (see Anderson column 3, lines 57-67, column 7, lines 43-47 and column 8, lines 59-66). It is inherent or at least obvious to one having ordinary skill in the art at the time the invention was made that, although not expressly disclosed by Anderson, the accumulated data stored, displayed or printed and used for analysis in the method of Anderson assesses a patient's cardiac vulnerability to sudden cardiac death because any arrhythmias present in the vectorcardiograph can be detected and classified and arrhythmias are a well known precursor to sudden cardiac death. The Examiner takes the position that a method, which classifies arrhythmias present in a patient's ECG signal, inherently assesses "vulnerability" to "sudden cardiac death" since an arrhythmia present in a patient's ECG indicates that a patient is more "vulnerable" to experiencing "sudden cardiac death". Anderson discloses the claimed invention as discussed above except that it is not specified that the method calculate a 3-D QRS-T angle from a set of orthoganalized X, Y and Z leads of the

ECG and then use the 3-D QRS-T angle to asses a patient's cardiac vulnerability to sudden cardiac death by calculating a variation between successively calculated 3-D QRS-T angles.

Kardys, however, teaches that the spatial QRS-T angle, read as the 3-D QRS-T angle since it is disclosed to be calculated from a set of orthoganalized X, Y and Z leads of the ECG, is a strong and independent predictor of cardiac mortality that is less susceptible to noise. Kardys also discloses that calculation of the 3-D QRS-T angle can be easily implemented on modern electrocardiographs, which are nowadays equipped with sufficient computing power. Kardys teaches that the abnormal 3-D QRS-T angles are associated with worse cardiac outcomes such as fatal cardiac events (see Kardys pages 1357-1364). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys to utilize a 3-D QRS-T angle calculated from a set of orthoganalized X, Y and Z leads of the ECG since such a modification would allow for assessment a patient's worsening condition and since such a modification may be easily implemented and is less susceptible to noise.

The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not further comprise conduction a time series analysis of the first and second values. Kaplan, however, teaches that is known to use a time series to quantify beat-to-beat variability in an ECG waveform in order to determine susceptibility to ventricular fibrillation (see Kaplan column 5, lines 12-23 and column 6, lines 1-22). Kaplan also discloses that an objective of the time series analysis on a plurality of beats is to derive a numerical parameter from the ECG, which is associated with susceptibility to ventricular fibrillation (see Kaplan Abstract and column 2, lines 25-30). Therefore, it would have been obvious to one

having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys and Kaplan to include a time series analysis in order to derive a numerical parameter associated with susceptibility to ventricular fibrillation.

22. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys and Kaplan as applied to claim 18 above, and further in view of Verrier '617. The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not further comprise using a cardiac parameter or heart rate variability in addition to the ECG signal to asses the patient's cardiac vulnerability to sudden cardiac death.

Verrier '617, however, discloses a method and apparatus for the non-invasive diagnosing of cardiac vulnerability to ventricular fibrillation that comprises evaluating heart rate variability in addition to T-wave alternans of the ECG signal (see Verrier '617 Title and Abstract). Verrier '617 discloses that heart rate variability is a measure of autonomic influence, which is a major factor in triggering cardiac arrythmias and that by simultaneous analysis of the ECG signal and heart rate variability allows for the extent and cause of cardiac vulnerability to be assessed so that drug therapy may be tailored per patient (see Verrier '617 column 4, lines 54-67 and column 5, lines 1-5). The Examiner takes the position that heart rate variability is synonymous with a cardiac parameter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys, Kaplan and Verrier '617 to include simultaneous evaluation of heart rate variability in addition to the ECG signal to better asses the patient's vulnerability to sudden cardiac death and to tailor a drug therapy as best to treat the patient.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

24. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica L. Reidel
Examiner
Art Unit 3766

12/12/06

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766